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10/516,781

12/03/2004

Silvio Aime

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/516,781 | Applicant(s) AIME ET AL. | |
| | Examiner D. L. Jones | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/10/08; 12/3/04; & 3/13/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11-13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 2,7-9,11,12 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/3/04; & 3/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/10/08 wherein claims 6, 10, and 14-16 were canceled and claims 1, 11, 12, and 19 were amended. In addition, the Examiner acknowledges the amendment filed 12/3/04 wherein the specification was amended.

Note: Claims 1-5, 7-9, 11-13, and 17-19 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds encompassed by Formulae I and II and uses thereof as set forth in claims 1, 11, 13, 17, 18, and 19.

APPLICANT'S ELECTION

3. Applicant's election with traverse of Group I filed 7/10/08 is acknowledged. The traversal is on the ground(s) that the document cited to break the unity of the invention (McBride et al, US Patent No. 5,620,675) does not disclose a compound within the pending claims. This is found non-persuasive because the original claims presented for examination did lack unity of invention as indicated by McBride et al. However, Applicant has now amended the claims such that the McBride et al document is no longer applicable. Thus, the restriction requirement is still deemed proper and is therefore made FINAL. Applicant is respectfully requested to review the 'Rejoinder Paragraph' included in the office action mailed 7/1/08. Should allowable subject matter be found, the claims will be rejoined as set forth in the Rejoinder Paragraph.

Note: A modified version of the restriction requirement is found below which excludes canceled claims and claims that were inadvertently placed in the wrong group.

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However, it should be noted that the overall restriction of the groups is the same. Thus, Applicant's response filed 7/10/08 is still applicable to the modified groups below.

Modified Groups

Group I, claim(s) 1-5, 7, 8, and 13, drawn to a MRI species of formula I.

Group II, claim(s) 9, drawn to a process of preparing MRI species.

Group III, claim(s) 11 and 12, drawn to intermediate compounds of formula II.

Group IV, claim(s) 17, drawn to a method of imaging organs/tissue.

Group V, claim(s) 18, drawn to a method of diagnosing tumors.

Group VI, claim(s) 19, drawn to a process of preparing an MRI species wherein the process steps are different from those of Group II above.

Furthermore, the Examiner acknowledges receipt of Applicant's elected species wherein D = gadolinium complexed with DTPA; p = 1; n = 0; N = glutamine; and m = 2. Thus, in Formula I, the spacer is absent and two glutamine substituents are attached to a single gadolinium-DTPA complex. Therefore, *claims 1, 3, 4, 5, and 13 read on Applicant's elected species*. Initially, Applicant's elected species was searched. However, because no prior art was found which could be used to reject Applicant's claims, the search was expanded to D = gadolinium complexed with DTPA; p = 1; n = 0; N = lysine; and m = 1. Thus, in Formula I, the spacer is absent and a single lysine substituent is attached to a single gadolinium-DTPA complex. Since, prior art was found which could be used to reject the claims, the search was not further expanded. Hence, the full scope of Group I has not been searched.

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WITHDRAWN CLAIMS

4. Claims 2, 7-9, 11, 12, and 17-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

102 REJECTIONS

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ranney (WO 95/14492).

Ranney discloses radioactive metal ion chelate conjugates (see entire document, especially, abstract). In particular, Ranney discloses a gadolinium-DTPA-lysine complex (abstract; page 73, Example 4) encompassed by the instant invention.

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Thus, both Applicant and Ranney disclose a composition wherein according to Applicant's Formula I, D is a gadolinium-DTPA complex; $p = 1$; $n = 0$; N = lysine; and $m = 1$. Thus, in Formula I, the spacer is absent and a single lysine substituent is attached to a single gadolinium-DTPA complex.

PRIORITY DOCUMENT

9. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

COMMENTS/NOTES

10. Applicant is reminded that while independent claim 1 which reads on Group I discloses steps that occur upon contact with the cells or cell surface, the patentability of a product claim is based upon the components of product, not the steps that occur once the composition comes in contact with a subject. Thus, the composition of independent claim 1 comprises D (a detectable MRI moiety), N (a molecule as set forth in independent claim 1), and optionally, a spacer moiety.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

October 27, 2008